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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/603,124	06/23/2000	Markus Pompejus	BGI-132CP	1469

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LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER
ZARA, JANE J

ART UNIT	PAPER NUMBER
1635	13

DATE MAILED: 02/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/603,124	POMPEJUS ET AL.	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1 136(a). In no event, however may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication even if timely filed may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *18-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 35-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application)

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

App

DETAILED ACTION

Claims 1-38 are pending in the instant application.

Election/Restriction

Claims 18-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

Applicant's election with traverse of Group I and SEQ ID NO: 1 in Paper No. 12 is acknowledged. The traversal is on the ground(s) that inclusion of up to ten sequences would not be a serious burden for examination. This is not found persuasive because expansive data bases must be searched in order to perform a thorough search for each sequence. For purposes of performing a thorough examination on the merits, therefore, the restriction to a single sequence is required.

The requirement is still deemed proper and is therefore made FINAL.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Denmark during period spanning July 8, 1999 through September 3, 1999. It is noted, however, that applicant has not filed a certified copy of any of the pending foreign applications as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 and 35-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims must stand alone and should not refer to figures or Appendices from the specification.

In claim 35, line 4, it is unclear what is meant by "are not or are not".

In claim 36, lines 2 and 3, it is unclear what is meant by "wherein the nucleic acid molecule is disrupted".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17 and 35-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification and claims do not indicate what distinguishing attributes are concisely shared by the members of the genera comprising an HA protein or a portion thereof, a fine chemical, an allelic variant, a homologue of at least 50% identity, a heterologous polypeptide, nucleic acid modifications (i.e. compared to those set forth in Appendix A or of SEQ ID NO: 1) or a modified regulatory region of a molecule. Nor does the specification describe elements which are essential to various functions of each claimed genus. The specification does not place any limit on the number of nucleic acid or amino acid substitutions, deletions, insertions and/or additions that may be made within each genus. The scope of the claims includes numerous structural variants, and each genus is highly variant because a significant number structural differences between genus members is permitted. Concise structural features that could distinguish compounds from others in each genus are missing from the disclosure. No common structural attributes identify the members of the various genera. The specification fails to teach or adequately describe a representative number of species in each genus such that the common attributes or characteristics concisely identifying members of each proposed genus are exemplified. The general knowledge and level of skill in the art do not supplement the omitted description because specific - not general - guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics concisely identifying members of the proposed genera, and because each genus is highly variant, the description provided for each genus is insufficient. One of skill in the art would reasonably conclude that the disclosure fails to

provide a representative number of species to describe the genera claimed. Thus, applicant was not in possession of the claimed genera.

Claims 1-17 and 35-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the construction of genomic libraries of Corynebacterium glutamicum ATCC 13032, and their subcloning into plasmids or cosmids, and their subsequent sequence determination, does not reasonably provide enablement for the production of fine chemicals from any and/or all isolated nucleic acids obtained from Corynebacterium glutamicum including SEQ ID NO: 1, nor homologues and allelic variants thereof, nor the production of polypeptides from any and/or all such nucleic acids, nor diagnosis of C. Diphtheria in a subject, nor the disruption of expression of any and/or all of these nucleic acids, nor any and/or all modifications of such nucleic acids, nor a determination of their regulatory regions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to the production of fine chemicals from any and/or all isolated nucleic acids obtained from Corynebacterium glutamicum including SEQ ID NO: 1, or from any homologues and allelic variants thereof, as well as the production of polypeptides from any and/or all such nucleic acids, the diagnosis of C. Diphtheria in a subject using such nucleic acids and variants, and the disruption of expression of any and/or all of these nucleic acids, as well as

any and/or all modifications of such nucleic acids, and a determination of their regulatory regions.

The following factors have been considered in determining that the specification does not enable the skilled artisan to make and/or use the invention over the scope claimed.

The state of the prior art and the predictability or unpredictability of the art. The determination of nucleic acid sequences derived from subcloning and sequencing of genomic Corynebacterium glutamicum from ATCC 13032 is not representative of the successful determination and delineation of any and/or homologues of 50% identity or more of such nucleic acids including SEQ ID NO: 1, or allelic variants, whereby fine chemicals are produced, polypeptides are expressed, diagnoses of C. Diptheriae is made and regulatory regions are identified.

The amount of direction or guidance presented in the specification AND the presence or absence of working examples. Applicants have not provided guidance in the specification toward methods of producing fine chemicals from any and/or all isolated nucleic acids obtained from Corynebacterium glutamicum including SEQ ID NO: 1, nor of determining any and/or all homologues and allelic variants thereof, nor the production of polypeptides from any and/or all such nucleic acids, nor diagnosis of C. Diphtheria in a subject, nor the disruption of expression of any and/or all of these nucleic acids including SEQ ID NO: 1 and its homologues, nor determining any and/or all modifications of such nucleic acids, nor determining their regulatory regions. The specification teaches the sequencing of genomic C. Glutamicum

from ATCC 13032 using plasmids or cosmids in E. Coli. One skilled in the art would not accept on its face the examples given in the specification of the sequencing of genomic C glutamicum from ATCC 13032 as being correlative or representative of producing fine chemicals from any and/or all isolated nucleic acids obtained from C. glutamicum, nor of determining any and/or all homologues and allelic variants thereof, nor the production of polypeptides from any and/or all such nucleic acids, nor diagnosis of C. Diphtheria in a subject, nor the disruption of expression of any and/or all of these nucleic acids, nor determining any and/or all modifications of such nucleic acids, nor determining their regulatory regions in view of the lack of guidance in the specification and known unpredictability associated with the ability to produce fine chemicals, express polypeptides, determine allelic variants and homologues, diagnose infections in an organism, disrupt expression of or determine regulatory regions of such a broad array of sequences, including all of the homologues of greater or equal to 50% identity with SEQ ID NO: 1, or any allelic variants thereof.

The breadth of the claims and the quantity of experimentation required. The breadth of the claims is very broad. The claims are drawn to the production of fine chemicals from any and/or all isolated nucleic acids obtained from Corynebacterium glutamicum including SEQ ID NO: 1, or from any homologues and allelic variants thereof, as well as the production of polypeptides from any and/or all such nucleic acids, the diagnosis of C. Diphtheria in a subject using such nucleic acids and variants, and the disruption of expression of any and/or all of these nucleic acids, as well as any and/or all modifications of such nucleic acids, and a determination

of their regulatory regions. In order to practice the invention over the scope claimed, it would require undue trial and error and undue experimentation beyond which is taught in the specification to practice the invention drawn to the production of fine chemicals from such a broad array of nucleic acid sequences, or to determine allelic variants or homologues of such a broad array of nucleic acids, including SEQ ID NO: 1, and further whereby the regulatory regions have been delineated, and diagnosis of C. Diptheriae in a subject has been obtained. The quantity of experimentation required to practice the invention as claimed would require the de novo determination of accessible methods of producing fine chemicals from SEQ ID NO: 1 and all allelic variants and homologues greater than or equal to 50 % identity with SEQ ID NO: 1, as well as all polypeptides encoded by such a broad array of sequences, and the de novo determination of the regulatory regions thereof, and further whereby diagnosis of C. Diphtheria in an organism has been obtained. Since the specification fails to provide any particular guidance for obtaining, characterizing and using such a broad array of compositions, and since determination of these factors for a particular nucleic acid sequence obtained from the genome of C. Glutamicum is highly unpredictable, it would require undue experimentation to practice the invention over the broad scope claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6-8, 10 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by either Kobayashi, Smith et al or Wachi.

Kobayashi teaches isolated nucleic acids of SEQ ID NO: 1, which nucleic acids encode portions of polypeptides from Corynebacterium glutamicum (See accession No. AB003132 and accompanying sequence alignment data).

Smith teaches nucleic acids of SEQ ID NO: 1, which nucleic acids encode portions of polypeptides from Corynebacterium glutamicum (SEQ ID NO: 30 of USPN 5,871,960, and accompanying sequence alignment data).

Wachi teaches nucleic acids of SEQ ID NO: 1, which nucleic acids encode portions of polypeptides from Corynebacterium glutamicum (See accession No.AB015023 and accompanying sequence alignment data).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ANDREW WANG
PRIMARY EXAMINER

JZ

February 19, 2002